UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL 1456 Master File No. 01-CV-12257-PBS Judge Patti B. Saris
THIS DOCUMENTS RELATES TO: *State of Montana v. Abbott Labs., Inc. et al.*, (D. Mont. No. CV-02-09-H-DWM) *State of Nevada v. American Home Products Corp., et al.*, (D. Nev. No. CV-N-02-0202-ECR)	

MEMORANDUM IN SUPPORT OF IMMUNEX CORPORATION'S MOTION TO DISMISS THE STATE OF MONTANA'S SECOND AMENDED COMPLAINT AND THE STATE OF NEVADA'S AMENDED COMPLAINT

[06735-0051/SL032530.177]

INTRODUCTION

The states of Montana and Nevada (the "States") allege virtually the same AWP claims as alleged by private plaintiffs in the Amended Master Consolidated Complaint ("AMCC"), plus the States have added AWP claims that pertain to the States' expenditures of Medicaid funds, and a few pages about defendants' alleged "Best Price" fraud under the federal Medicaid program. As articulated in the consolidated memorandum in support of defendants' motion to dismiss Montana's Second Amended Complaint ("Mont. Compl.") and Nevada's Amended Complaint ("Nev. Compl."), the States' claims are deficient on many grounds applicable to all defendants.

As to Immunex, the States' claims fail for lack of an intelligible theory with respect to multiple-source drugs and lack of the particularity requirements of Rule 9(b). The Court should dismiss with prejudice Montana's and Nevada's claims against Immunex.

I. The States' AWP Claims Relating to Multiple-Source Drugs Should Be Dismissed with Prejudice.

As the Court concluded in ruling on defendants' motions to dismiss the MCC, "multiple source drugs do not fit the paradigm described in the complaint." *In re Pharmaceutical Indus. Average Wholesale Price Litig.*, 263 F. Supp. 2d 172, 194 n.11 (D. Mass. 2003). Multiple-source drugs do not fit the paradigm described in the MCC, the AMCC, or the most recent complaints filed by Montana and Nevada. The States assert two types of AWP claims relating to multiple-source drugs: the States' *parens patriae* claims on behalf of private payors and Medicare beneficiaries and the States' claims on behalf of the Montana and Nevada Medicaid programs. The *parens patriae* claims relating to multiple-source drugs are identical in substance to claims asserted by the private plaintiffs in the MDL, so the Court should dismiss these claims for the reasons set forth in the consolidated

memorandum in support of defendants' motion to dismiss the AMCC. *See* Consol. Mem. in Supp. of Defendants' Motion to Dismiss the AMCC at 36-38.

The States' claims on behalf of their Medicaid programs relating to multiple-source drugs are equally flawed. Both Montana and Nevada acknowledge that under the Medicaid program, "reimbursement for multiple-source drugs for which there are at least three suppliers" is based on a dispensing fee plus "an amount equal to 150 percent of the ***lowest AWP published*** . . . an amount called the 'Federal Upper Limit.'" Mont. Compl. ¶ 188; Nev. Compl. ¶ 151 (emphasis added). Montana concedes that it has incorporated the "Federal Upper Limit" into its definition of "maximum allowable cost," a flat reimbursement rate for multiple-source drugs. Mont. Compl. ¶ 188 (citing Mont. Admin. R. 37.86.1101(3)). The States allege that Immunex manufactured the multiple-source drugs leucovorin calcium and methotrexate sodium,[1] Mont. Compl. ¶ 465; Nev. Compl. ¶ 286, yet fail to explain how Immunex could have manipulated a system where reimbursement was not directly tied to Immunex's AWPs, but rather to the lowest AWP published. Montana and Nevada have not pled any specifics as to the lowest AWP published for these multiple-source drugs. The Court should dismiss with prejudice the States' AWP claims relating to multiple-source drugs.

II. The States' AWP Claims Relating to All of Immunex's Drugs Fail for Lack of Rule 9(b) Particularity.

In a multi-defendant case, the plaintiff must plead with particularity the role of each defendant in the alleged fraud. Fed. R. Civ. P. 9(b) provides as follows: "In all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity." Virtually all of the States' claims (e.g., deceptive trade practices, racketeering,

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[1] As of 2001, the generic equivalent (thiotepa) of Immunex's Thioplex® was also available for sale by a manufacturer other than Immunex.

Medicaid fraud, and false claims) sound in fraud and are subject to Rule 9(b)'s particularity requirement. *See Konstantinakos v. Federal Deposit Ins. Corp.*, 719 F. Supp. 35, 38 (D. Mass. 1989). Rule 9(b) requires that plaintiffs identify "the who, what, when, where, and how of the alleged fraud." *United States ex rel. Franklin v. Parke-Davis*, 147 F. Supp. 2d 39, 46 (D. Mass. 2001) (internal quotation marks and citations omitted). Montana and Nevada have failed to comply with the requirements of Rule 9(b), instead relying on sweeping allegations about "defendants" or "drug manufacturers" without providing specifics.

The States fall far short of meeting the minimum pleading requirements established by the Court, namely that each plaintiff must "clearly and concisely allege with respect to each defendant: (1) the specific drug or drugs that were purchased from defendant, (2) the allegedly fraudulent AWP for each drug, and (3) the name of the specific plaintiff(s) that purchased the drug." 263 F. Supp. 2d at 194. Instead, the States allege as follows:

- The States allege generally that "Immunex manufactures several drugs reimbursed by the Montana [or Nevada] Medicaid Program and which are purchased by citizens of the [States]," without alleging the names of any citizen that purchased a single drug from Immunex. Mont. Compl. ¶ 82; Nev. Compl. ¶ 54.
- The States list certain published AWPs from 1997 to 2002 for certain Immunex drugs in Appendix A to the States' Complaints, without specifically alleging *how* each Immunex AWP was fraudulent.
- As to Immunex's single source drugs Thioplex®, Novantrone®, and Leukine®, the only additional reference to these drugs is from a document that notes that "[w]e need to take into account that in some . . . markets they get AWP or AWP plus a percentage, in others, depending on the markup of the patient population, they may only get the 80% Medicare allowable," Mont. Compl. ¶ 473; Nev.

Compl. ¶ 294, without explaining how this document supports the States' conclusory assertion that Immunex made a "conscious effort to increase the spread for providers and intermediaries." *Id.*

- As to Immunex's single source drugs Thioplex®, Novantrone®, and Leukine®, the States fail to allege what the actual prices were for comparison to the published AWPs.
- As to Thioplex® and Novantrone®, the States fail to allege that these drugs had any competitors against whom the "spread" could have been manipulated to move market share.
- As to Thioplex® and Leukine®, the States fail to allege any specific spread between the *Red Book*-published AWPs and the "actual AWPs," and as to Novantrone®, allege a spread of only 21% without explaining how that was fraudulent. Mont. Compl. ¶ 479; Nev. Compl. ¶ 300.
- As to Immunex's multiple-source drugs leucovorin calcium and methotrexate sodium, the States list various "phony AWPs" and the "spread created" for these products, while ignoring that reimbursement for multiple-source drugs under both Medicare and Medicaid is not directly tied to a single manufacturer's AWP. Mont. Compl. ¶ 475; Nev. Compl. ¶ 296.

The States, represented by the same counsel representing the private plaintiffs in this MDL action, having reviewed the voluminous documents that Immunex produced to private plaintiffs, have simply cut and pasted their claims relating to Immunex from the claims in the AMCC. The Court should dismiss the States' claims with prejudice and without further leave to amend. *See Hayduk v. Lanna*, 775 F.2d 441, 445 (1st Cir. 1985).

III. The States' Best Price Claims Relating to All of Immunex's Drugs Fail for Lack of Rule 9(b) Particularity.

As to Immunex, the Best Price claims of Montana and Nevada fail Rule 9(b). The sections of the States' Complaints entitled, "Defendants Have Reported False AMP And Best Price Information, Resulting In The Underpayment Of Drug Rebates," contain no allegations relating to Immunex. *See* Mont. Compl. ¶¶ 612-634; Nev. Compl. ¶¶ 392-403. The States fail to identify even one allegedly fraudulent "Best Price" report involving Immunex and fail to identify even one allegedly fraudulent "Best Price" or "AMP" reported by Immunex for a single drug. Instead, these states rely on sweeping allegations against the entire pharmaceutical industry. *See, e.g.*, Nev. Compl. ¶ 392 ("In keeping with their artificial price information scheme, each defendant did not report the actual Best Price or AMP, but instead (i) reported higher prices. . . . ").

A federal magistrate judge recently recommended dismissal under Rule 9(b) of similarly deficient "Best Price" claims. *See LaCorte v. Merck & Co.*, No. 99-3807, slip op. at 7 (E.D. La. Aug. 27, 2003) (noting that the complaint "alleges no particular dates of [best price] report submissions and does not refer to a single instance where Merck submitted prices to the government that were distinct from those paid by the hospitals"). This Court should dismiss with prejudice the States' cursory "Best Price" claims against Immunex.

CONCLUSION

For the foregoing reasons and those set forth in the consolidated memorandum and individual defendant briefs, the Court should dismiss the claims of Montana and Nevada against Immunex with prejudice.

DATED: September 15, 2003.

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